



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

m2525n
Food and Drug Administration
555 Winderley Place, Suite 200
Maitland, Florida 32751

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref: Customs Entry No. 660-0443999-9
Product: Coffee Mugs

WARNING LETTER

FLA-99-50

April 9, 1999

Art Neaf, President
Florida State Distributors
4601 S.W. 34th Street
#102
Orlando, Florida 32811

Dear Mr. Neaf:

The Food and Drug Administration (FDA) requested to examine a shipment of coffee mugs offered for entry into the United States by your firm on March 5, 1999, under the above referenced entry number, and determined that the entire shipment was not available for FDA examination. The original entry consisted of [REDACTED] cases of coffee mugs. We determined that only [REDACTED] cartons were held for FDA examination and that [REDACTED] cases were distributed without an FDA "May Proceed" or a "Notice of Release". Regulation 1.90, Title 21, Code of Federal Regulations, (21 CFR 1.90) requires the importer to hold an entry intact pending receipt of a "May Proceed Notice" or "Release Notice" from FDA. We requested the U. S. Customs Service (Customs) to order redelivery on [REDACTED] cases of this shipment (copies enclosed).

Failure to promptly correct this violation and prevent future violations may result in regulatory action without further notice such as seizure, injunction, or automatic detention of future shipments. It is your responsibility, as the importer, to ensure that imported products meet all the requirements of the Federal Food, Drug, and Cosmetic Act and the regulations promulgated thereunder.

We request a response in writing within fifteen (15) working days of receipt of this letter of the specific steps you have taken to correct the violation, including an explanation of each step being taken to prevent the recurrence of the violation.

Mr. Art Neaf
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Your written reply should be addressed to the Food and Drug Administration, Attention: Kendall W. Hester, Compliance Officer, 555 Winderley Place, Ste. 200, Maitland, Florida 32751, telephone no. (407) 475-4730.

Sincerely,



Douglas D. Tolen
Director, Florida District

Enclosure

cc: District Director
U. S. Customs Service
164 E. 7th Avenue, Ste. 101
Tampa, Florida 33605

Sack & Menendez
P. O. Box 986
Tampa, Florida 33601